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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/666,581	09/18/2003	Yoshikazu Tobinaga	27698.001	9168
21878	7590	06/17/2005	EXAMINER	
KENNEDY COVINGTON LOBDELL & HICKMAN, LLP			AHMED, AAMER S	
214 N. TRYON STREET			ART UNIT	
HEARST TOWER, 47TH FLOOR			PAPER NUMBER	
CHARLOTTE, NC 28202			3763	

DATE MAILED: 06/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/666,581

Applicant(s)

TOBINAGA ET AL.

Examiner

Aamer S. Ahmed

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 18 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 1/28/2005.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## DETAILED ACTION

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5, 7- 10, 14-16 and 19-30 rejected under 35 U.S.C. 102(b) as being anticipated by Park et al (Pub. No.: US 2002/0082543 A1).

As to Claim 1, Park describes an applicator for applying functional substances into human skin, comprising: a base, a plurality of microneedles fixed to said base and projecting therefrom a distance sufficient to penetrate into the skin, said microneedles being made of a material that is capable of disintegration and dispersion into the skin, and a functional substance carried by said microneedles for delivery by said microneedles into the skin. (See Figure 5).

Similarly Park describes Claim 2, as an applicator as described above, and further characterized by having the functional substance distributed in the material of the microneedles. (See Page 3 paragraph 0046).

Moreover as to Claim 3, Park describes that the functional substance is distributed homogeneously throughout the microneedles. (See Column 3 paragraph 0046).

In addition, as to Claim 4, Park recites that the functional substance is encapsulated in the microneedles. (See Page 3 Paragraph 0045).

Furthermore, as to Claim 5, Park teaches that the base and microneedles are integrally molded from the same material. (See Page 3 Paragraph 0040).

Also, as to Claim 7, Park discloses that the microneedles are generally cone shaped. (See Figure 5).

Similarly, as to Claims 8, 9 and 10, Park describes that the microneedles may be square, polygonal or elliptical in cross-section. (See Page 4 Paragraph 0054).

Furthermore, as to Claim 14, Park discloses that the microneedles have tips that are knife-shaped. (See Figure 5).

In addition, as to Claim 15, Park discloses that the microneedles contain microcontainers containing a functional substance, and the microcontainer is contained within the microneedle. (See Figure 3).

Moreover, as to Claim 16, Park discloses that the microneedles are formed with barbed tips and the microcontainers are disposed in the barbed tips. (See Figure 3).

Also as to Claim 19, Park discloses that the microneedles project from said base a distance sufficient to penetrate the stratum corneum. (See Page 9 Paragraph 0119 ).

Furthermore, as to Claim 20 Park teaches that the microneedles project approximately 0.5 to 500 $\mu$ m from the base. (See Page 5 Paragraphs 0057-0059).

Similarly, as to Claims 21,22, 23 and 24 Park describes that the microneedles are generally cone shaped, (See Figure 5), with a diameter as base approximately 0.1 to 100 $\mu$ m and the microneedles that are square, polygonal or partially elliptical in cross-section having sides or diameters approximately 0.1 to 100 $\mu$ m at base. (See Page 5 Paragraphs 0057-0059).

In addition, as to Claim 25, Park describes that the microneedles are of sufficient projection to penetrate the dermis. (See Page 8 Paragraph 101).

Moreover as to Claim 26 Park discloses that the microneedles project approximately 500 to 5,000 $\mu$ m from the base. (See Page 5 Paragraphs 0057-0059).

Similarly, as to Claims 27-30, Park describes, that the microneedles are generally cone shaped, (See Figure 5), with a diameter as base approximately 0.1 to 1,000 $\mu$ m and the microneedles that are square, polygonal or partially elliptical in cross-section having sides or diameters approximately 0.1 to 100 $\mu$ m at base. (See Page 5 Paragraphs 0057-0059).

Thus Park reasonably appears to teach and disclose every element of these claims and therefore anticipates them.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Park et al (Pub. No.: US 2002/0082543 A1). Referring to claims 6, it would have been an obvious matter of design choice to distribute the functional substance homogeneously throughout the base and microneedles. Applicant has not disclosed that the specific inclusion of the second recess solves any stated problem that invention would perform equally well with the functional substance contained within the microneedle.

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Park et al (Pub. No.: US 2002/0082543 A1) in view of D'Ussel (Pub. No.: US 20040010237 A1).

Park describes an applicator for applying functional substances into human skin as mentioned above in reference to Claim 1. Park fails to disclose that the needle material is substantially sugars which dissolve in the human body.

D'Ussel describes a needle made substantially of sugars that dissolves within the human body. (See Page 1 Paragraph 14).

It would have been obvious to one of ordinary skill in the art at the time of invention by the applicant to modify the applicator for applying functional substances into human skin with the sugar needle of D'Ussel in order to make a more biodegradable needle of the type disclosed by D'Ussel.

Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Park et al (Pub. No.: US 2002/0082543 A1) in view of Arias et al (US 20020133129 A1). Park describes an applicator for applying functional substances into human skin as mentioned above in reference to Claim 1. Park fails to disclose microneedles with a constricted intermediate ends. Arias does describe microneedles with a constricted intermediate ends. (See Figure 15L).

It would have been obvious to one of ordinary skill in the art at the time of invention by the applicant to modify the applicator for applying functional substances into human skin with the constricted intermediate end design of Arias in order to make a more breakable microneedle tip of the type disclosed by Arias.

Similarly Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Park et al (Pub. No.: US 2002/0082543 A1) in view of Arias et al (US 20020133129 A1). Park describes an applicator for applying functional substances into human skin as mentioned above in reference to Claim 1. Park fails to disclose microneedles with thin outer portions and thick inner portions adjacent the base with the outer portions remaining in the skin.

Arias does describe microneedles with thin outer portions and thick inner portions adjacent the base with the outer portions remaining in the skin. (See Figure 15I).

It would have been obvious to one of ordinary skill in the art at the time of invention by the applicant to modify the applicator for applying functional substances into human skin with the varied thickness design of Arias in order to make a more separable microneedle tip of the type disclosed by Arias.

Finally Claims 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Park et al (Pub. No.: US 2002/0082543 A1) in view of Sherman et al ('281).

Park describes an applicator for applying functional substances into human skin as mentioned above in reference to Claim 1. Park fails to disclose microneedles having capillary recesses in outer the portions, or capillary recesses extending along a central axis of said microneedles and are open at the outer ends of said microneedles.

Sherman does describe microneedles with capillary recesses in outer the portions and the capillary recesses extending along a central axis of said microneedles and are open at the outer ends of said microneedles. (See 38 Figure 4).

It would have been obvious to one of ordinary skill in the art at the time of invention by the applicant to modify the applicator for applying functional substances into human skin with the microneedles having capillary recesses in outer the portions as described by Sherman in order to enhance retention of the functional substances for delivery into the skin.

### *Conclusion*

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

U.S. Pub. No. 20030095582A1	Ackley
U.S. Pub. No. 20020138049 A1	Allen
U.S. Pat. No. 6334856 B1	Allen
U.S. Pub. No. 20040146611 A1	Arias
U.S. Pat. No. 6770480 B1	Canham
U.S. Pub. No. 20020193754 A1	Cho
U.S. Pat. No. 6767341 B2	Cho
U.S. Pat. No. 6689100 B2	Connelly
U.S. Pub. No. 20020193729 A1	Cormier
U.S. Pat. No. 6881203 B2	Delmore
U.S. Pat. No. 6780171 B2	Gabel
U.S. Pat. No. 6652478 B1	Gartstein



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U.S. Pat. No. 3964482 A	Gerstel
U.S. Pub. No. 20030135167 A1	Gonnelli.
U.S. Pat. No. 4206757 A1	Grandadam
U.S. Pub. No. 20040087893 A1	Kwon
U.S. Pat. No. 6113581 A	Levy
U.S. Pat. No. 6517521 B1	Ly
U.S. Pub. No. 20030208138 A1	Olson
U.S. Pub. No. 20030208167 A1	Prausnitz
U.S. Pat. No. 6503231 B1	Prausnitz
U.S. Pat. No. 6611707 B1	Prausnitz
U.S. Pat. No. 6743211 B1	Prausnitz
U.S. Pub. No. 20030199812 A1	Rosenberg
U.S. Pat. No. 6623457 B1	Rosenberg
U.S. Pat. No. 6790372 B2	Roy
U.S. Pat. No. 6835184 B1	Sage
U.S. Pat. No. 4921475 A	Sibalis
U.S. Pub. No. 20020099356 A1	Unger
U.S. Pat. No. 6603987 B2	Whitson
U.S. Pat. No. 6558361 B1	Yeshurun
U.S. Pat. No. 6565532 B1	Yuzhakov
U.S. Pat. No. 6256533 B1	Yuzhakov

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WO2004000389A2

Kwon

WO98/28037

Theeuwes

DE2825232C2

Roussel-Uclef

DE69720057T2


Theeuwes et al.

DE10065168

Bracht et al.

WO2004/033021A1

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